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AUDIT REPORT FOR THE CZECH REPUBLIC
JUNE 8 THROUGH JUNE 15, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of the Czech Republic's meat inspection system from June 8 through June 15, 2000. The two establishments certified to export red meat to the United States were audited. Both of these were slaughter/processing establishments.

The last audit of the Czech Republic's meat inspection system was conducted in March 1999. Two establishments were audited: one was acceptable (Est.12), and one was evaluated as acceptable/re-review (Est.15). The principal concerns with the system at that time were the following:

1. Fecal contamination was observed on a carcass in the cooler at Establishment 15. This deficiency was not found during this new audit.

2. Paint flakes and rust were observed on beef quarters and rails in the cooler at Establishment 15. This was not a problem during the new audit.

The Czech Republic has been approved to export of meat to the U.S. During calendar year 1999/2000, the Czech Republic did not export any meat products to the U.S. Currently, the Czech Republic is under APHIS restriction for BSE.

PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with the Czech Republic's national meat inspection officials to discuss oversight programs and practices, including enforcement activities. There were only two approved establishments for export to the U.S. from the Czech Republic, so no records review of establishments at inspection headquarters was performed. The second was conducted by on-site visits to the two establishments. The third was a visit to a residue/bacteriology laboratory, performing analytical testing of field samples for the national residue testing program and culturing field

samples for the presence of microbiological contamination with *Salmonella*. The country was not using private laboratories for microbiological testing.
Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. The Czech Republic's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials. This was not the case in the Czech Republic.

RESULTS AND DISCUSSION

Summary

Based on the performance of the individual establishments, the Czech Republic's"In-Plant Inspection System Performance" was evaluated as In-Plant System Controls In Place.

Effective inspection system controls were found to be in place in both establishments; one of these (Establishment 12) was recommended for re-review. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

Entrance Meeting

On June 9, an entrance meeting was held at the Prague offices of the Czech Republic's State Veterinary Administration, and was attended by Dr. Jozef Holejsovsky, General Director, Chief Veterinary Officer; Dr. Milan Malena, Sectional Director of Veterinary Hygiene, Public Health Protection and Ecology; Dr. Eduard Slanec, Head of Division, Department of Veterinary Hygiene, Public Health and Ecology; Dr. George Kuna, Senior Veterinary Officer, State Veterinary Administration of the Czech Republic; Dr. Ghias Mughal, Branch Chief, International Audit Staff; and Dr. Oto Urban, International Audit Staff Officer, USDA/FSIS. Topics of discussion included the following:

1. Disease status according to APHIS

2. Status of the 1999 residue results and 2000 plan

3. Control of *Listeria monocytogenes*

4. Personnel changes in the Czech Republic Inspection Service

Headquarters Audit

There had been no changes in the organizational structure since the last U.S. audit of the Czech Republic's inspection system in March 1999. There had been a change on the level of General Director of the State Veterinary Administration: The previous Director, Dr. Kozak, had been replaced by Dr. Jozef Holejsovsky.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications, in order that the FSIS auditor (hereinafter called "the auditor") could observe and evaluate the process. However, the review of both establishments was performed by the in-plant Inspector In Charge rather than by the Czech counterparts to U.S. Circuit Supervisors. The official responsible for Est.15 was not present for the audit; the one responsible for Est.12 was present but declined to lead the audit.

The records review conducted during the on-site audit of both establishments, focused primarily on food safety hazards, and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Label approval records such as generic labels, and animal raising claims.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records including examples of written procedures for withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by the Czech Republic as eligible to export meat products to the United States were full-time State Veterinary Administration employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Both establishments were certified to export meat products to the United States at the time this audit was conducted and both were visited for on-site audits. In both establishments, the Czech inspection system controls and the establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of the accredited laboratory. For residue/microbiology testing of meat and meat products, the Czech Republic uses only the government laboratory.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The State Veterinary Institute Laboratory in Jihlava was audited on June 6, 2000. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency). The only deficiency observed was that the residue analyst's name did not appear in the documentation of the procedures that she had performed.

The Czech Republic's microbiological testing for *Salmonella* was being performed in the government laboratory in Jihlava. No deficiencies were found in this area.

Establishment Operations by Establishment Number

Both establishments (12 and 15) were conducting beef and pork slaughter and boning, cutting, curing, drying, and smoking operations; cooked sausages and loaves; and shelf-stable canned products.

SANITATION CONTROLS

Based on the on-site audits of the establishments, the Czech Republic's inspection system had controls in place for: water potability records, chlorination procedures, back-siphonage prevention, hand washing facilities, sanitizers, separation of establishments, pest control programs, pest control monitoring, temperature control, lighting, operations work space, inspector work space, ventilation, facilities approval, equipment approval, over- product equipment, product-contact equipment, other product areas, dry storage areas, antemortem facilities, welfare facilities, outside premises, personal dress and habits, personal hygiene practices, cross-contamination prevention, product transportation, effective maintenance programs, preoperational sanitation, and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with only occasional minor variations, such as that preoperational findings and corrective actions were not adequately described in Establishment 15.

Sanitary Dressing Procedures

Fecal contamination, hair and oil were observed on carcasses in the boning room in Establishment 12. No immediate corrective action was taken, by either establishment officials or the IIC until the auditor pointed out the need.

Equipment Sanitizing

Washing of dirty offal trays was deficient in both establishments. Corrective actions were immediately taken in both establishments.

Product Handling and Storage

Small pieces of foreign material (probably paint) were found on carcasses in the boning room in Establishment 15. Corrective action was taken by the establishment personnel.

Product Reconditioning

1. In Establishment 12, an employee was observed to fail to wash his hands after contaminating them with product that fell onto on the floor, and to continue to work without reconditioning this contaminated product. Corrective action was not immediate.
2. Contamination of viscera by contact with the floor was observed in Establishment 12. Corrective action was taken.

Operational Sanitation

Water from meat tub wheels was falling into the product during the product dumping and mixing operation in Est.12. No corrective action was taken.

Cross-contamination

Carcasses were contacting each other on the suspect line in Establishment 12.

Over-Product Ceilings

Non-dripping condensation, not over carcasses was observed in Establishment 15. Corrective action was taken by the establishment officials.

Other Product Areas

Flaking paint and rusty rails were observed in coolers and the boning room in Establishment 15 and flaking paint was found on carcasses in the boning room in Establishment 12. Corrective action was taken by the establishment officials.

Pest Control

Spider webs were observed on the slaughter floor in Establishment 15.

ANIMAL DISEASE CONTROLS

With the exceptions listed below, the Czech Republic's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

Post-Mortem Inspection

Some inspectors in both establishments were not adequately inspecting the lymph nodes.

No outbreaks of animal diseases with public-health significance had been reported since the previous U.S. audit. The Czech Republic was under APHIS restriction on BSE, because of possible trade import of BSE infected product. The last case of Classical Swine Fever in the domestic swine population was reported in 1997. Classical Swine Fever was present in the wild boar population.

The Czech Republic had developed an efficient system to trace violative animals back to the farms of origin.

RESIDUE CONTROLS

The Czech Republic's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Czech inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals. There had been one Sulfa violation (Sulfadimidin) in an animal slaughtered at Establishment 15. It was properly handled by the Czech Republic's Veterinary Services.

SLAUGHTER/PROCESSING CONTROLS

The Czech inspection system had controls in place to ensure adequate requirements for humane slaughter, post-mortem disposition, condemned product control, restricted product control, returned and rework product, pre-boning trim, ingredients identification, control of restricted ingredients, formulations, packaging materials, laboratory confirmation, label approvals, special label claims, inspector monitoring, processing schedules, processing equipment, processing records, empty can inspection, filling procedures, container closure exam, interim container handling, post-processing handling, incubation procedures, processing defect actions by the establishment, and inspection processing control.

Neither establishment had an appropriate designated area for boneless meat reinspection.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements. The only exceptions were that the "zero tolerance" policy for fecal contamination was not enforced and that on-site verifications were not being performed in both establishments.

Testing for Generic *E. coli:*

The Czech Republic had adopted the FSIS regulatory requirements for *E. coli* testing. Both establishments were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements with the following differences:

1. *E. coli* samples were collected by the Veterinary Services of the Czech Republic.
2. The choice of carcasses for sampling was made by the IIC in both establishments.
3. Both establishments were sponging carcasses for *E. coli* sampling, while they were using excision sample criteria (m, M) for the evaluation of the test results. Establishments sponging carcasses are to evaluate *E. coli* test results using a statistical process control technique of their own making.
4. The site for sample collection was not designated in the written procedure in Establishment 12.

Both establishments had adequate controls in place to prevent meat products intended for domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the Czech inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat products from other counties for further processing] were in place and effective in ensuring that products produced by the two establishments were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Neither establishment had an appropriate designated area for boneless meat reinspection.

Testing for *Salmonella* Species

Both establishments were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The Czech Republic had adopted the FSIS regulatory requirements for *Salmonella* testing. The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

Species Verification Testing

At the time of this audit, the Czech Republic was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by the Czech equivalent of Circuit Supervisors. All were veterinarians with several years of experience in meat inspection.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were sometimes announced and sometimes not announced in advance, and were conducted, at times by individuals and at other times by a team of reviewers, at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the District Veterinary Headquarters, and were routinely maintained on file for a minimum of 3 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, a commission is empowered to conduct an in-depth review, and the results are reported to the headquarters of the State Veterinary Administration in Prague for evaluation; they formulate a plan for corrective actions and preventive measures.

During the country audit, the IICs took the lead in both establishment reviews. In Establishment 12, the monthly supervisory report did not describe findings and in Establishment 15, deficiencies were recorded at the District Veterinary Headquarter Data Base and the IIC did not have access to them.

Enforcement Activities

Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishments, inspection supervision as required, and adequate controls for security items, shipment security, species verification, and products entering the establishment from outside sources. Enforcement and implementation of *Salmonella* testing was performed according to U.S. requirements. Additionally, immediate action was taken by the State Veterinary Administration of the Czech Republic in case of any food safety violations, disease outbreaks, or any criminal activity.

Exit Meetings

An exit meeting was conducted in the offices of the State Veterinary Administration in Prague on June 14. The Czech participants were Dr. Josef Holejsovsky, General Director and Chief Veterinary Officer; Dr. Milan Malena, Sectional Director of Veterinary Hygiene, Public Health Protection and Ecology; Dr. Jiri Drapal, Veterinary Hygiene, Public Health Protection and Ecology; and Dr. Jiri Kuna, Senior Veterinary Officer, State Veterinary Administration of the Czech Republic; The U.S. participants were: Dr. Ghias Mughal, Branch Chief, International Audit Staff; and Dr. Oto Urban, International Audit Staff Officer. The following topics were discussed:

1. Fecal and hair contamination were observed in the boning room in Establishment 12. Corrective action was not immediate, but was eventually taken by IIC, when auditor pointed out the need.

2. Reconditioning of product that contacted the floor in Establishment 12 was inadequate. No corrective action was taken by either establishment management or Inspection Service.

3. Water from meat tub wheels was falling into product during the dumping and mixing operation in Establishment 12. No corrective action was taken.

4. SSOP performance and HACCP and *E. coli* implementation deficiencies observed in both establishments were discussed in detail.

5. No corrective actions had been documented in the monthly supervisory reports in Establishment 12, and no copies of the monthly supervisory reports were made available to the IIC in Establishment 15.

   Following this meeting, Dr. Mughal and Dr. Urban attended a short meeting with the Agriculture Specialist, Ms. Petra Choteborska at the U.S. Embassy in Prague. The topic of the discussion was audit findings and corrections by the Czech Inspection Service.

CONCLUSION

The inspection system of the Czech Republic was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Two establishments were audited: one was acceptable, and one was evaluated as acceptable/re-review. The deficiencies encountered during the on-site establishment audits, in the establishment which was found to be acceptable, were adequately addressed to the auditor's satisfaction. Several deficiencies as noted in the previous section, were not followed by immediate corrective action.

Dr. Oto Urban
International Audit Staff Officer

(signed) Dr. Oto Urban

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing
E. Laboratory audit form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)
H. FSIS Response(s) to Foreign Country Comments (when it becomes available)

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. Identified	7. Docu-mentation done daily	8. Dated and signed
12	√	√	√	√	√	√	√	√
15	√	√	√	√	√	√	√*	√

Est.15/7* Descriptions of deficiencies and corrective actions were too general.

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
12	√	√	√	√	√	no				no		
15	√	√	√	√	√	no	√	√	√	no		√

Est. 12/6, 15/6 There was no CCP for fecal contamination.
Est. 12/10, 15/10 On-site verification by the establishment was missing.

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
12	√	√*	√**	√	√	no	no	√	√	√
15	√	√*	√	√	√	no	no	√	√	√

12/2, 15/2 Veterinary Services was collecting *E. coli* samples in the Czech Republic
12/3 The written procedure did not designate the establishment location for sample collection but it had been performed in the cooler.
12/6, 15/6 The establishment was sponging carcasses for *E. coli* sampling, but was using excision-sample criteria for evaluation of test results.
12/6, 15/6 The carcass selection was being made arbitrarily by the IIC.

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
12	√	√		√	√	√
15	√	√	√	√	√	√